

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-29V

UNPUBLISHED

CANDICE LOMBARDO,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: November 17, 2023

Special Processing Unit (SPU);
Entitlement to Compensation; Ruling
on the Record; Findings of Fact;
Influenza ("Flu"); Shoulder Injury
Related to Vaccine Administration
(SIRVA);

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioner.

Sarah Black Rifkin, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On January 4, 2021, Candice Lombardo filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") caused by an influenza ("flu") vaccine administered on November 8, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons set forth below, I find that Petitioner is entitled to compensation.

¹ In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

On June 2, 2022, Respondent filed a status report arguing that this case is not appropriate for compensation and requesting 45 days to file a Rule 4(c) report. ECF No. 26. Respondent maintains that Petitioner does not meet the severity requirement of the Vaccine Act, and cannot establish a Table claim because she has not established onset of her injury within forty-eight hours of vaccination. *Id.* at 7-10. Petitioner filed a motion for a ruling on the record on September 19, 2022. Petitioner's Motion for Ruling on the Record and Brief in Support of Damages ("Mot."), ECF No. 31. Respondent opposed the motion on November 17, 2022, reiterating the arguments set forth in the Rule 4(c) Report. Respondent's Response to Petitioner's Motion for Ruling on the Record ("Opp."), ECF No. 33, at 1-6. Petitioner filed a reply on November 29, 2022. Petitioner's Reply Brief in Support of Petitioner's Motion for Ruling on the Record and Brief in Support of Damages ("Reply"), ECF No. 34. The matter is ripe for resolution.

II. Petitioner's Medical Records

Petitioner's past medical history includes reports of carpal tunnel syndrome and chronic left breast pain related to implants which interfered with her daily activities and work, but no reports of left shoulder issues. Ex. 1 at 123.

Petitioner received a flu vaccine in her left shoulder on November 8, 2019, at a plastic surgeon's office. Ex. 1 at 127. Three days later, on November 11, 2019, she saw her primary care provider, Dr. Bhawna Gupta, for a previously-scheduled visit. Ex. 1 at 134, Ex. 10 at 172. She complained of left-sided breast pain that had been worsening over the past four years, along with neck and upper back pain, and left-hand numbness. Ex. 1 at 134-40. There was no reference to shoulder pain or a flu vaccine.

Petitioner first contacted Dr. Gupta's office with complaints of left arm pain on November 20, 2019, reporting that she had a flu shot on November 7, 2019. Ex. 10 at 180. The record also states that "she saw Dr. Gupta on 11/11/19 and brought the pain up." *Id.* During a call-back from Dr. Gupta, Petitioner reported that she had a flu vaccine in her left arm, and "following that" she had "pain locally, with numbness in the left arm and forearm [that] radiates from the left upper arm down." Dr. Gupta prescribed a course of prednisone. *Id.*

On December 1, 2019, Petitioner visited an urgent care center, reporting a month-long history of left arm pain "that ha[d] been ongoing since she received her flu shot at the beginning of November." Ex. 3 at 3. She also reported limited range of motion and weakness. *Id.* Bursitis and adhesive capsulitis was suspected.

Petitioner subsequently called Dr. Gupta to schedule an appointment on December 2, 2019, and noted that she was “still having significant pain in her arm since her flu shot.” Petitioner saw Dr. Gupta that same day with reports of pain “3 days after she got the flu shot in her L arm.” Ex. 10 at 187. She reported her pain as “whole arm” that radiated to her upper back. *Id.* An examination showed reduced strength and range of motion in her left shoulder. *Id.* at 189. She was diagnosed with impingement syndrome, prescribed Mobic, Ultram, and a Medrol Dosepak. *Id.* at 192.

On December 6, 2019, Petitioner visited an orthopedics walk-in clinic. Ex. 4 at 18. She reported shoulder pain radiating to her forearm that started “about day or 2: after a flu vaccine. *Id.* An examination showed “slight discomfort” with abduction, and she was diagnosed with an axillary nerve injury. *Id.* at 19.

Petitioner returned to the orthopedic clinic on December 16, 2019, and saw Dr. David Martin. Ex. 4 at 11. Petitioner reported that she developed “pain and stiffness in her left shoulder soon after a flu shot” that started “about day or 2” after the vaccination. *Id.* at 11, 18. Petitioner’s shoulder was tender, and her range of motion was reduced. Dr. Martin stated Petitioner likely had “a frozen shoulder/adhesive capsulitis” but could also have “a bone bruise or even a small underlying hematoma or abscess....” *Id.* at 11.

An MRI performed on January 15, 2020, showed an infraspinatus strain, with some possible low-grade partial tearing and associated inflammation. Ex. 1 at 171. A few days later, she reviewed the MRI results with Dr. Martin, who noted that Petitioner had “significant fluid in the infraspinatus which either is a borderline full-thickness tear or perhaps even a tear at the musculotendinous junction.” Ex. 4 at 5. Dr. Martin recommended a surgical repair. *Id.*

Petitioner again reported ongoing shoulder pain that “started after getting flu shot a few months ago” to Dr. Gupta at her annual exam on January 24, 2020. Ex. 10 at 281. She also reported that Dr. Martin stated she had a “partial tear” and needed surgery, but she wanted to get a second opinion. *Id.*

Over the next ten months, Petitioner saw medical practitioners on at least two occasions. On May 4, 2020, Petitioner had a telehealth visit with Dr. Gupta for medical clearance to return to work at a dental office. Ex. 10 at 309. Petitioner also saw her gynecologist at a telehealth visit on May 6, 2020, to discuss genetic testing and her ongoing left breast pain. Ex. 8 at 100.

On October 14, 2020, Petitioner called Orthopedic Specialty Group reporting ongoing left shoulder pain and seeking a second opinion. Ex. 9 at 7. Petitioner saw Dr. James FitzGibbons on November 10, 2020. Ex. 7 at 4. She related her pain to the 2019 flu vaccine, stating that she “had a flu shot” and from that time she “knew that something ‘was not right.’” *Id.* Petitioner also stated that she felt excruciating pain for eleven months after the injection, but her shoulder improved after she took time away from work due to the COVID-19 pandemic. *Id.* An examination showed positive impingement signs and discomfort with certain range of motion. *Id.* at 5. She received a Kenalog injection, and was instructed in home exercises. *Id.* at 6.

Petitioner has submitted two affidavits in support of her claim. Ex. 2, 11. Therein, she states that she received a flu vaccine on November 8, 2019, and immediately felt pain in her shoulder. Ex. 2 at 2, Ex. 11 at 2. Petitioner also stated that her delay in seeking additional treatment after January 2020 was due to the COVID-19 pandemic. Ex. 2 at 4, Ex. 11 at 2.

Vincent Lombardo (Petitioner’s husband) and Emma Zerella (Petitioner’s mother) also submitted affidavits. Mr. Lombardo stated that Petitioner experienced pain the day she received the flu vaccine. Ex. 12 at 2. Ms. Zerella stated that Petitioner called her the day she received the flu vaccine, and told her she was in significant pain. Ex. 13 at 2.

III. Fact Findings and Ruling on Entitlement

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner’s injury, and the lack of other award or settlement,³ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A

³ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42

Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A. Severity Requirement

The first issue to be resolved is whether Petitioner has demonstrated that she suffered “residual effects or complications of [the injury alleged] for more than six months after the administration of the vaccine,” as required for eligibility under the Vaccine Program. Section 11(c)(1)(D)(i).

There is no dispute that Petitioner received the flu vaccine on November 8, 2019, and she therefore must demonstrate by preponderant evidence that her residual symptoms continued at least through May 8, 2020 (assuming onset of pain the day of vaccination). *See, e.g., Herren v. Sec'y of Health & Human Servs.*, No. 13-100V, 2014 WL 3889070, at *2 (Fed. Cl. Spec. Mstr. July 18, 2014); *see also Hinnefeld v. Sec'y of Health & Human Servs.*, No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's injury resolved less than two months after onset).

The record establishes that Petitioner's initial treatment occurred over approximately three months, between November 11, 2019 and January 24, 2020, followed by a ten month gap. However, when she returned for additional treatment she specifically noted that her shoulder pain started after a flu shot. Ex. 7 at 4. Further, she explained that she had time away from work, which assisted in a reduction of her symptoms. *Id.*

Respondent argues that Petitioner did not seek treatment for her shoulder over a ten month period, but the record establishes that she did attend several telehealth visits and an in-person exam. Opp. at 2-3. Petitioner contends that her gap in treatment was reasonable due to the COVID-19 pandemic and symptom improvement due to reduced work. Further, the appointments cited by Respondent were for unrelated medical issues, including an appointment to be cleared to work and a gynecology exam. It is understandable that she would not mention her shoulder pain during these visits. I also note that the COVID-19 Pandemic began that same winter, and is a reasonable explanation for why treatment visits may have ceased for at least some of this time.

The overall record constitutes a sufficient showing of severity to meet the preponderance evidentiary standard. It is likely that Petitioner's symptoms persisted into

the spring of 2020, despite the cessation of treatment and subsequent gap. However, the light history of treatment also suggests a mild injury - which will likely impact damages in this case.

B. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

1. Petitioner Had No Prior Left Shoulder Condition or Injury that would Explain her Symptoms

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent does not dispute that Petitioner meets this criterion, and I find that she has demonstrated a lack of history of pain, inflammation, or dysfunction of her left shoulder that would explain her symptoms.

2. Onset of Petitioner's Injury Occurred within Forty-Eight Hours of her Vaccination

The medical records preponderantly establish onset of injury close-in-time to vaccination. Petitioner first reported shoulder pain twelve days after her November 8, 2019, vaccination, stating that she had shoulder pain following her flu vaccine. Ex. 10 at 180. Thereafter, Petitioner continued to link her shoulder pain temporally to the flu vaccine. See Ex. 10 at 187 (record from December 2, 2019, stating that Petitioner had significant pain in her arm "since her flu shot"); Ex. 4 at 11, 18 (record from December 16, 2019, stating she developed pain and stiffness in her shoulder "soon after a flu shot").

Respondent argues that Petitioner's statements are vague and never identified a specific timeframe for onset of her shoulder symptoms. Opp. at 4-6. Even so, a finding of proper onset can be made based on such a record. Program petitioners are not required to marshal records setting forth with chronographic specificity the precise day and hour that their onset manifested. As noted above, Petitioner consistently linked her shoulder pain to the November 8, 2019, flu vaccine.

Further, the relevant medical records show that Petitioner reported shoulder pain in a relatively timely manner, when measured from the date of vaccination. Thus, Petitioner first began to complain of shoulder pain within twelve days of the vaccine and did not attribute her pain to any other injury or cause. It is common for SIRVA petitioners

to delay seeking treatment, thinking the injury will resolve on its own, especially since patients are often told by medical providers at the time of vaccination to expect some soreness and pain for a period of time after. And individuals also often misconstrue the nature of their injury, and therefore fail to inform treaters of all specific facts relevant to onset until later. Here, the added detail of onset did not “wait” for months before being provided, but began to be reported in a reasonable time post-vaccination. And Petitioner affirmatively and repeatedly linked her shoulder pain to the flu vaccine.

Respondent also argues that Petitioner failed to report shoulder pain on November 11, 2019, when she saw Dr. Gupta for a previously scheduled visit, undermining her assertion that symptoms began within forty-eight hours of the vaccination. Opp. at 4. It is not unexpected that Petitioner did not raise her shoulder pain with Dr. Gupta on November 11, as that appointment was for a specific and unrelated issue, *i.e.*, left-sided breast pain. Ex. 1 at 134-35.

Accordingly, there is preponderant evidence that establishes the onset of Petitioner’s left shoulder pain more likely than not occurred within 48-hours of vaccination.

3. Petitioner’s Pain was Limited to her Left Shoulder

Petitioner’s pain was limited to her left shoulder. Respondent does not contest this aspect of Petitioner’s claim, and there is nothing in the records to suggest otherwise.

4. There is No Evidence of Another Condition or Abnormality

The last criteria for a Table SIRVA state that there must be no other condition or abnormality which would explain a petitioner’s current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent does not contest this aspect of Petitioner’s claim, and there is nothing in the records to suggest that any such condition or abnormality exists.

C. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received a flu vaccine intramuscularly on November 8, 2019, in the United States. Ex. 1 at 123-27; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration

within the United States or its territories). There is no evidence that Petitioner has collected a civil award for her injury. Ex. 2 at 2; Section 11(c)(1)(E) (lack of prior civil award).

Based upon all of the above, Petitioner has established that she suffered a Table SIRVA. Additionally, she has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

IV. Damages

Petitioner requests \$85,000.00 for pain and suffering. Mot. at 30, Reply at 11. I decline to decide damages at this time, and instead instruct the parties to discuss whether damages can be decided informally. However, if the parties cannot come to an agreement within 30 days, additional briefing may be ordered.

Conclusion

In view of the evidence of record, I find that there is preponderant evidence that Petitioner satisfies the QAI requirements for a Table SIRVA. Further, based on the evidence of record, I find that Petitioner is entitled to compensation.

Accordingly, the parties shall file a Joint Status Report by December 18, 2023, indicating whether a brief attempt at settlement discussions would be productive.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master